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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,989	05/24/2006	Rami Evron	PHUS030466US2	1420

38107 7590 08/17/2010
PHILIPS INTELLECTUAL PROPERTY & STANDARDS
P. O. Box 3001
BRIARCLIFF MANOR, NY 10510

EXAMINER

SANEI, MONA M

ART UNIT	PAPER NUMBER
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2882

MAIL DATE	DELIVERY MODE
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08/17/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,989	Applicant(s) EVRON, RAMI	
	Examiner MONA M. SANEI	Art Unit 2882	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3-16,20 and 21 is/are allowed.
- 6) ☒ Claim(s) 8-10,12-14 and 17-19 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 1 and 3-7, 13, and 15-21 are objected to because of the following informalities:

- In claim 1, line 6, “patent” should read - -patient- -.
- In claim 3, line 1, “apparatus” should read - -device- -.
- In claim 4, line 1, “apparatus” should read - -device- -.
- In claim 5, line 1, “apparatus” should read - -device- -.
- In claim 6, line 1, “apparatus” should read - -device- -.
- In claim 7, line 1, “apparatus” should read - -device- -.
- In claim 13, line 1, “noise” should read - -noise level- -.
- Claim 15, a method claim, depends from claim 1, a system claim.
- In claim 20, last line, “selected the” should read - -the selected- -.
- Claims 16-19 and 21 are objected to by virtue of their dependencies.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 12-14 and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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- In claim 12, line 2, the phrase “a target required noise level” is indefinite insofar as it is unclear whether the phrase is referring to a new target required noise level or to the targeted noise level recited in parent claim 8, line 5.
- In claim 17, line 3, “the diagnostic examination” lacks proper antecedent basis.
- In claim 19, line 1, “the target noise level” lacks proper antecedent basis.
- In claim 19, line 2, “the noise level” lacks proper antecedent basis.
- Claims 13, 14, and 18 are rejected by virtue of their dependencies.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kleinman (US 4597094) in view of Mahnken et al. (Detection of Colanary Calcifications: Feasibility of Dose Reduction with a Body Weight-Adapted Examination Protocol; August 2003; AJR; 181:533-538) and Hsieh (US 5696807).

- Regarding claims 8 and 10, Kleinman a method including selecting a target required radiation dose of an x-ray tube in accordance with physical parameters of a patient to be examined and performing an x-ray diagnostic examination of the patient with an x-ray beam with the selected radiation doses (col. 2, lines 49-66; col. 4, lines 19-45; fig. 1).

However, Kleinman fails to teach that the physical parameter is a body mass index for the patient.

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Mahnken et al. teaches that a physical parameter is a body mass index for a patient (pg. 533, see sections labeled, “objective” and “results”; pg. 533, col. 2, last para; pg. 534, col. 1, para 1; pg. 534, col. 3, last para; figs. 2 and 4; it is noted that $BMI = \text{weight}/\text{height}^2$).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the method of Kleinman as suggested by Mahnken et al. since one would have been motivated to make such a modification to reduce overall radiation exposure to the patient (see section “objection”) as implied by Mahnken et al.

However, Kleinman as modified by Mahnken et al. further fails to teach that the target required radiation dose is determined based on a constant selected in accordance with a targeted noise level.

Hsieh teaches that a target required radiation dose is determined based on a constant selected in accordance with a targeted noise level (Hsieh teaches selecting a desired noise level for an image to generate an x-ray modulating factor that is then used to modulate the x-ray tube current (abstract). Examiner takes a broadest reasonable interpretation of the term “constant” in the claim and takes the position that since a single desired noise level is set and used for the tube current modulation, a target required radiation dose is determined based on a constant selected in accordance with a targeted noise level).

It would have been obvious to one having ordinary skill in the art at the time of the invention to further modify the method of Kleinman as suggested by Hsieh since one would have been motivated to make such a modification to reduce patient dose while maintaining image quality (col. 3, lines 32-39) as implied by Hsieh.

- Regarding claim 9, Mahnken et al. as modified teaches a method as recited above.

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However, Mahnken et al. fails to teach that the body mass index is squared.

At the time the invention was made, it would have been an obvious matter of design choice to one having ordinary skill in the art to square the body mass index as applicant has not disclosed that squaring the body mass index provides an advantage, is used for a particular purpose, or solves any stated or long standing problem in the art. One of ordinary skill in the art, furthermore, would have expected Mahnken et al.'s method and applicant's method to perform equally well with either the body mass index as taught by Mahnken et al. or the square of the body mass index as recited in claim 9 because either physical parameter would function in providing a body-adapted tube current time setting means for reducing radiation dose to the patient.

Therefore, absent any showing of criticality, it would have been obvious to one having ordinary skill in the art to modify the method of Mahnken et al. such that the body mass index is squared as such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Mahnken et al.

Allowable Subject Matter

4. Claims 1-7, 15, 16, 20, and 21 are allowed.

The following is an examiner's statement of reasons for allowance:

- Regarding claim 1, the prior art fails to teach or fairly suggest an x-ray diagnostic imaging device including a dose selection processor for calculating a target maximum patient dose based on $C(\text{patient weight} \div (\text{patient height})^2)^2$, wherein C is a constant determined based on a target required noise level, in combination with all the other limitations of the claim.

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- Regarding claim 20, the prior art fails to teach or fairly suggest a method comprising multiplying the body mass index squared by a constant to calculate a tube current for the x-ray tube, wherein the constant is selected in accordance with a noise level, selecting a radiation dose of an x-ray tube in accordance with the calculated tube current, and performing an x-ray diagnostic examination of the patient with an x-ray beam based on selected the radiation dose, in combination with all the other limitations of the claim.

- Claims 2-7, 15, 16, and 21 are allowable by virtue of their dependencies.

- Claims 17-19 would be allowable by virtue of their dependencies on allowable claim 1 if rewritten to overcome the 35 U.S.C. § 112 ¶2 claim rejection set forth above.

5. Claims 11-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

- Regarding claim 11, the prior art fails to teach or fairly suggest a method of diagnostic imaging including squaring the body mass index and multiplying the body mass index squared by the constant to calculate a tube current for the x-ray tube, in combination with all the other limitations of the claim.

- Claims 12-14 contain allowable subject matter by virtue of their dependencies.

Response to Amendment

6. By virtue of the amendments to the drawings, spec, and claims, the drawing, spec, and claim objections set forth in the Non-Final Rejection mailed March 26, 2010, have been overcome.

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7. By virtue of the amendments to the claims, all but the 35 U.S.C. § 112 ¶2 claim rejections of claims 17 and 19 set forth in the Non-Final Rejection mailed March 26, 2010, have been overcome.

Response to Arguments

8. Applicant's arguments with respect to the claim have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONA M. SANEI whose telephone number is (571)272-8657. The examiner can normally be reached on M-F 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward J. Glick can be reached on (571) 272-2490. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mona M Sanei/
Examiner, Art Unit 2882

/Hoon Song/
Primary Examiner, Art Unit 2882